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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,563	04/16/2004	Mark A. Hoffman	CRNC	2108

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,563	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant's election of species of ethnicity in the reply filed on 11/13/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An action on the merits of claims 1-21, as they read on the elected species, follows.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 4 and 5 are so dark that details of the Figures can not be discerned. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a computer system comprising only "components" for performing computational steps. The "system" is not limited to comprise any hardware or other physical limitations and thus encompass a program. A computer program, per se, is not statutory subject matter. See MPEP 2106, in particular Section IV. The claims encompass nonstatutory subject matter, and are therefore rejected.

Claim Rejections - 35 USC § 112, 1st para

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the specification nor the prior art teach how to determine the likelihood pf a person having a gene variant indicative of an atypical clinical event (a) in the absence of any genetic test result and/or (b) in the

absence of a step of determining if a test result value indicates the presence of a polymorphism/variant which is KNOWN to be associated with or indicative of an atypical clinical event.

With regard to (a), the specification indicates in paragraph 38 that if a patient has not had a genetic test performed relevant to the genetic trait, the system may order a test. The specification further discloses in paragraphs 40-41 that personal information or demographic information may be used to determine the likelihood of a variant based on genetic predisposition of the demographic population to which the patient presumably belongs. However, the claims do not recite determining the likelihood of a gene variant for a patient in a specific demographic subset of a population; i.e. for a "general patient," nor do they recite using personal or demographic information to determine the likelihood that a person has a gene variant indicative of an atypical event. Claims 1 and 15, in fact, recite that if a genetic test result value is NOT available, for a patient, then an output indicating the likelihood that the person has a gene variant is generated. In the absence of any knowledge that a patient has a gene or gene variant associated with clinical agent information (i.e. if the genetic test has not yet been performed, therefore there is no "genetic test result value"), then it would be impossible for one skilled in the art to determine whether there is a likelihood that the person has a gene variant indicative of an atypical clinical event. With regard to (b), the specification discloses in paragraph 36 that a system determines if an association exists between a clinical agent and a certain gene or genes such that an interaction between the agent and gene(s) would be expected to result in an atypical clinical event. However,

different individuals may display phenotypes, or characteristics which indicate differential expression of genes. It is well known, for example ,that different expression patterns of the gene which produces melatonin result in different skin tones. All humans have the gene for melatonin, but in albinos and very fair-skinned people, the gene is not expressed or is expressed at extremely low levels. Merely determining whether a patient has the "melatonin gene" would not provide information as to a patient's likelihood to have an "atypical clinical event" if exposed to UV therapy. The specification, in paragraph 46 and in Figures 2 and 6 that a polymorphism table may be searched/accessed wherein the table indicates that particular polymorphisms are known to be associated with specific agents and atypical clinical events regarding those agents. The instant claims do not recite searching a table of polymorphisms known to be associated with agents and atypical clinical events, nor any other limitations with regard to a "genetic test result value" which is KNOWN to be associated with a clinical agent, gene variant, and/or atypical clinical event. There are no working examples in the specification for performing a method using ONLY the method steps recited in the instant claims.

The prior art of JUDSON et al. (US 6,931,326) teaches a method of predicting an individual's clinical response to a treatment based on the individual's genotype or haplotype. In this case, however, the prediction is based on comparison to clinical trial data or a table correlating haplotypes and clinical response (col. 28). The prior art does not teach, anywhere, a priori determination of an atypical clinical event based on the absence of a genetic test result value.

The level of skill in the art is acknowledged to be high; however the level of unpredictability in associating genotypes, of haplotypes with specific clinical results is also high. The prior art of JUDSON et al. (US 6,931,326) teaches that symptoms and responses to treatments may have more than one underlying cause (col. 28, lines 46-55), thus presenting evidence that making associations between clinical responses and haplotypes is not trivial. SHIMADA et al. (US 5,989,844) teaches that a single CYP2 gene oxidizes more than thirty drugs, and that rates of genetic alterations occur at rates of up to 30% (col. 1, lines 33-42), thus also teaching that associating polymorphisms (altered genes) with responses to specific clinical agents is difficult. While it is possible to determine correlations between a polymorphism or particular haplotype and an "altered" or unusual drug response, the teachings of the prior art clearly support a high level of variability across populations and within populations.

Given the high level of unpredictability in the art for determining if a polymorphism is associated with an atypical clinical event (response) to a clinical agent, even where a polymorphism is KNOWN, and the lack of teaching in the either the specification or the prior art for how to determine whether a patient has a likelihood of a gene variant indicative of an atypical clinical event is the absence of a KNOWN correlation between a gene and such an event and/or a clinical agent, it would require undue experimentation for one skilled in the art to perform the claimed method. As the method is not enabled, then a computer or computer readable medium comprising instructions for running the method are also not enabled.

Claim Rejections - 35 USC § 112, 2nd para

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a recited relationship between a clinical agent, or clinical agent information and a output including information that a person has a gene variant. There is no connection between clinical agent information and either a genetic test value or the output, therefore the connection between the various claim elements is unclear, and the claims are indefinite.

Claims 2, 9, and 16 recite the phrase "a variation from the risks of the presence of a polymorphism in the general population" which is nonsensical. One does not generally indicate a variation FROM the risks of the presence of a polymorphism. One may calculate or determine, etc. the risk that a person may have a polymorphism, OR one may calculate the likelihood that a person has a variation in a gene based on population results. However, the phrase recited does not make sense in the context of the claim, therefore the claims are indefinite.

Claims 4, 11, and 18 recite a "further comprising" step, but each claim fails to recite where or when in the parent claim the new step is intended to occur. As the

relationship of the "further" step to the steps/instructions recited in the respective parent claims is unclear, claims 4, 11, and 18 are indefinite.

Claim 5, 12, and 19 recite that hereditary information "is obtained..." It is unclear whether "obtaining" medical information is intended to be a method step/instruction or a limitation of the data. If the former, then applicant is reminded that method steps and instructions for method steps should be recited using active, positive claim language. If the latter, then it is unclear what limitation of the method/program is intended by reciting a source for the data.

Claim 15 recites the phrase "comprising the steps of" in line 3. It is unclear what is to comprise steps, as no method is recited in the claim. Lines 1-2 recite "instructions for controlling a computer" but does not recite instructions for running a method. As it is unclear what is to comprise steps, claim 15 is indefinite.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
1/21/07